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Supreme Court of the United States

OCTOBER TERM, 1965

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMERICAN HOME PRODUCTS CORPORATION; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BAXTER LABORATORIES, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U.S.A.) INC.; CARTER PRODUCTS, INC.; CUTTER LABORATORIES; THE DOW CHEMICAL COMPANY; HOFFMANN-LA ROCHE INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; CHAS. PFIZER & CO., INC.; PHILIPS ROXANE, INC.; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; G. D. SEARLE & CO.; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES; STERLING DRUG INC.; THE UPJOHN COMPANY; VALE CHEMICAL COMPANY, INC.; WARNER-LAMBERT PHARMACEUTICAL COMPANY; PHARMACEUTICAL MANUFACTURERS ASSOCIATION, *Petitioners,*

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, *Respondents.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, *Respondents*.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Petitioners pray that a writ of certiorari issue to review the judgments of the United States Court of Appeals for the Third Circuit in its cases No. 15055 and No. 15054.

OPINIONS BELOW

The opinions of the Court of Appeals, as yet unreported, appear at Appendix A, p. 1a, *infra* (case No. 15055), and Appendix B, p. 10a, *infra* (case No. 15054). The opinion of the United States District Court for the District of Delaware (Chief Judge Caleb M. Wright) is reported at 228 F. Supp. 855 and appears at Appendix C, p. 12a, *infra*.

JURISDICTION

The judgment of the Court of Appeals in its case No. 15055 was entered on November 1, 1965. Appendix D, p. 28a, *infra*. Its judgment in No. 15054, a cross-appeal decided on the same record from the District Court, also was entered on November 1, 1965. Appendix E, p. 29a, *infra*. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

I

Federal officials promulgated and published in the Federal Register regulations for the enforcement of a statute. The regulations command all companies in the prescription drug industry to take specified action, and the Federal officials propose to implement the regulations. Compliance by these companies will cause them grave and irreparable injury. Noncompliance, on the other hand, will render the companies subject to civil and criminal prosecutions, seizure proceedings and harmful administrative actions. The question is whether, on the complaint of these companies, the legality of the regulations can be determined under the Declaratory Judgment Act and the Administrative Procedure Act.

II

Whether, under 28 U.S.C. § 1391(e), the statute recently enacted to liberalize venue requirements in actions against Federal officials, a corporation may be a resident of, and thus entitled to sue in a Federal District Court in, a state other than the state of its incorporation?

STATUTES AND REGULATIONS INVOLVED

Statutes:

Declaratory Judgment Act, 28 U.S.C. §§ 2201-02:

"§ 2201. Creation of remedy.

"In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

"§ 2202. Further relief.

"Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment."

Administrative Procedure Act, § 10, 60 Stat. 243 (1946), 5 U.S.C. § 1009:

"Sec. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

"(a) Right of review.—Any person suffering legal wrong because of any agency action, or ad-

versely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

"(b) Form and venue of action.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

"(c) Reviewable acts.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority."

Judicial Code, § 1391(e), 28 U.S.C. § 1391(e):

"§ 1391. Venue generally.

* * * * *

"(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United

States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides, or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action."

The foregoing statutory provisions govern the jurisdictional and procedural questions presented. The issue on the merits involves Section 502(e)(1) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1050 (1938), as amended by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U.S. C. § 352(e)(1), and Section 502(n) of that Act, added by § 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U.S.C. § 352(n), which appear at Appendix F, p. 31a, *infra*.

Regulations:

Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, §§ 1.104(g), 1.105(b), 28 Fed. Reg. 6375, 6376 (1963), 21 C. F. R. §§ 1.104(g), 1.105(b) (1965):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g) (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

"§ 1.105 Prescription-drug advertisements.

* * *

"(b) (1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."

STATEMENT

Petitioners are thirty-seven companies that manufacture and distribute prescription drugs and the Pharmaceutical Manufacturers Association ("PMA"), an association of which these companies and other prescription

drug companies are members. (R. 5a).[1] Each prescription drug company is directly affected by the challenged regulations. In the regular course of business it affixes labels to its prescription drugs and distributes labeling and advertising material in connection with such drugs. (R. 6a). Each company generally assigns a proprietary (brand) name to each prescription drug which it distributes, and these brand names appear on printed matter (including labels, labeling and advertising) relating to the particular prescription drug. (R. 8a).

Proceedings below

On June 20, 1963, after a formal rule making proceeding in accordance with Section 4 of the Administrative Procedure Act, 60 Stat. 238 (1946), 5 U. S. C. § 1003, regulations issued by the respondent Larrick, Commissioner of Food and Drugs, were published in the Federal Register. 28 Fed. Reg. 6375.[2] These regulations, as will be developed in more detail below, require that on all printed matter the established (generic) name of a prescription drug must be repeated each time the drug's proprietary name is used, no matter how many times the proprietary name is mentioned in a particular label, labeling piece or advertisement. Petitioners objected to this "every time" requirement when it was proposed in the rule making proceeding, but respondent Larrick refused to alter his proposal.[3]

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[1] "R." references are to the pages of the Joint Appendix printed for use in the Court of Appeals. Nine copies of the Joint Appendix have been filed with the Clerk of this Court pursuant to Rule 21(4).

[2] The regulations were stated to be issued under the authority delegated to Commissioner Larrick by the Secretary of Health, Education and Welfare. See 28 Fed. Reg. 6375.

[3] Proposed regulations were published on February 14, 1963, 28 Fed. Reg. 1448. In response, the petitioning companies, either individually or through PMA, submitted comments contending, *inter alia*, that respondents could not lawfully impose the "every time" requirement. (R. 10a-11a). Petitioners' contention was rejected by the respondents when the final regulations were issued.

Shortly after the regulations issued, petitioners filed a complaint in the United States District Court for the District of Delaware, asserting that the respondents were not authorized to impose the "every time" requirement and requesting a declaratory judgment to that effect and an injunction against enforcement of the regulations. (R. 3a-16a). The District Court's jurisdiction was invoked under Sections 1331 and 1337 of the Judicial Code, 28 U. S. C. §§ 1331, 1337, the Declaratory Judgment Act and Section 10 of the Administrative Procedure Act. (R. 3a).

Respondents moved to dismiss on jurisdictional and procedural grounds and for summary judgment if the merits should be reached. (R. 17a-20a). Petitioners filed a cross-motion for summary judgment. (R. 21a-22a). The case was heard on these motions. No answer was filed. No affidavits were filed by the respondents disputing any of the factual allegations in the complaint.

Of the thirty-eight petitioners, there were twelve—the PMA and eleven individual companies incorporated in Delaware (see R. 3a-5a)—as to which venue was clearly proper. The District Court held that a justiciable controversy was presented and rejected other jurisdictional arguments which respondents interposed as obstacles to an adjudication on the merits. The District Court reached the merits, held the regulations invalid, and enjoined enforcement of the regulations. (R. 66a-67a). The Court dismissed from the action those petitioners not incorporated in Delaware.

Cross-appeals were taken by the respondents and by those petitioners not incorporated in Delaware to the United States Court of Appeals for the Third Circuit. On respondents' appeal (case No. 15055), the Court of Appeals, in an opinion by District Judge Weber, held that no justiciable

controversy was presented because the regulations were "interpretive" and there had been no threat of prosecution. Accordingly, as to petitioners incorporated in Delaware, the Court did not reach the other jurisdictional issues decided by the District Court nor did it reach the merits. The District Court's venue ruling—dismissing from the action those petitioners not incorporated in Delaware—was affirmed by the Court of Appeals in its case No. 15054. The Court of Appeals has stayed the issuance of its mandate in both cases.

Nature of the regulations

As has been noted, the regulations at issue here were adopted after a formal rule making proceeding and were published in the Federal Register. 28 Fed. Reg. 6375. They were entitled "Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act." *Ibid.* They were made effective upon their publication. *Id.* at 6377.

Section 1.104(g) of the regulations ordered that the established (generic) name of a prescription drug "shall accompany each appearance" of that drug's brand name on labels and labeling for the drug.[4] The same requirement was imposed for advertisements of prescription drugs by Section 1.105(b) of the regulations. These regulations are applicable to advertisements and to "brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, house organs, literature reprints, and similar pieces of printed matter." § 1.105 (*l*), 28 Fed. Reg. 6377, 21 C. F. R.

[4]The established or generic name of a drug is defined in Section 502(e)(2) of the Act, added by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U. S. C. § 352(e)(2). Under that section, the established name of a drug may be a "common or usual name," an "official title" used in an "official compendium," or an "official name" designated by the Secretary under Section 508 of the Act, added by § 111(a) of the Drug Amendments of 1962, 76 Stat. 789, 21 U. S. C. § 358.

§ 1.105(*l*). Each time the brand name of a drug appears on any of these items (which include every piece of printed matter relating to the drug), the regulations require that its established name also be printed.

Compliance with these mandatory regulations would require each company to cease the distribution of printed matter which did not contain an "every time" mention of the established name, to destroy such material and to prepare new material in its place that would be more difficult to read and comprehend and would injure that company's business. (R. 13a-14a). Under Sections 302-04 of the Act, 52 Stat. 1043 (1938), as amended, 21 U. S. C. §§ 332-34, noncompliance with the regulations subjects each company to seizure proceedings, under which valuable drugs can be forfeited, and to criminal prosecutions and injunction proceedings. (R. 9a-10a).[5] Respondents can also attempt to enforce the regulations by refusing to approve the marketing of "new drugs" under Section 505 of the Act, 52 Stat. 1052 (1938), as amended, 21 U. S. C. § 355, and by refusing to certify each batch of antibiotics under Section 507 of the Act, 59 Stat. 463 (1945), as amended, 21 U. S. C. § 357, unless related printed matter complies with the "every time" requirement. See pp. 8a-9a, *infra*.

These drastic remedies can be invoked—even though the drugs are perfectly safe and effective, and even though

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[5]Indeed, Section 1.105 (k) of the regulations, 28 Fed. Reg. 6377, 21 C. F. R. § 1.105(k), provides that any advertisement not in compliance with the "every time" requirement "shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement . . . to be misbranded under section 502(a) of the act." Sections 301(a) and (b) of the Act, 52 Stat. 1042 (1938), as amended, 21 U. S. C. §§ 331(a), (b), prohibit the "misbranding" of any drug and the introduction into commerce of any "misbranded" drug, and Sections 302-04 of the Act specify the sanctions for violating Section 301.

the established name appears "prominently" on every page in the required type size and no doctor or patient is misled—solely on the ground that the established name does not appear every single time the proprietary name is used.

During the course of argument in the District Court, the mandatory nature of the regulations was emphasized, as the following colloquy reveals:

> "The Court: Mr. Goodrich [counsel for respondents], when your department makes a regulation, I certainly hope that you intend for the drug industry to obey those regulations.
>
> "Mr. Goodrich: We do indeed, sir.
>
> "The Court: If not, you take whatever steps are necessary to enforce them.
>
> "Mr. Goodrich: But the enforcement in the setting of a real case, where we have a piece of promotional material before us, is entirely different from an abstract question which is presented here." (R. 24a).

Respondents' counsel left no doubt that respondents intended petitioners to comply with the regulations and that noncompliance would call into play the drastic enforcement provisions of the Act.

REASONS FOR GRANTING THE WRIT

I

An industry is here confronted with regulations promulgated by Federal officials to enforce a statute carrying severe civil and criminal sanctions. In the opinion of petitioners, with which the District Court agreed, these regulations are contrary to the statute and not authorized by it. Unless there is a means of presenting to a court at once the question whether these regulations are lawful, each member of the industry has two choices: it can comply with the regulations, incurring substantial expense and changing its way of doing business, despite its belief that

the regulations are invalid; or it can defy the regulations, suffer months of delay in clearing applications to market "new drugs" and in obtaining certificates for batches of antibiotics, and await the unilateral decision of enforcement officials as to when, how, and against whom an attempt will be made to impose severe criminal or civil sanctions. Under these circumstances, as stated by the District Court, "to bar the courts to plaintiffs [petitioners] would be to do an injustice." P. 21a, *infra*.

If the Government succeeds in barring the courts to petitioners, thus preventing a straight-forward immediate test of the regulations, an industry confronted with illegal regulations will be obliged as a practical matter to engage in a type of guerrilla warfare with the Government. The Government, having promulgated the regulations, will wait a period of time in the hope that some companies, concerned with the possibility of administrative retaliation in the event of noncompliance, will comply with the regulations even though they believe in good faith that the regulations are illegal. After the illegal regulations have been in effect for some time and there have been some instances of compliance, the Government then at its own time and at its own convenience will select an individual member of the industry for a test case based on an egregious and nontypical example for the purpose of demonstrating the "validity" of the regulations. The Government will cite the facts that the regulations have long been in effect without challenge and that members of the industry have complied with the regulations. By this process of delay and attrition, the Government can create a situation where the regulations have acquired apparent validity although their inherent illegality remains the same. This is no way for Government in a democratic society to deal with those subject to its power.

The basic issue in this case is whether an industry confronted with illegal action by Federal officials should not

have its day in court in order that it can proceed in accordance with an established rule of law equally applicable to all members of the industry.

The Court of Appeals determined that the members of regulated industries are not entitled to their day in court—that in spite of a clear declaration that the regulations would be enforced, the Federal courts have no jurisdiction under either the Declaratory Judgment Act or the Administrative Procedure Act even to consider whether the regulations are within the statutory authority of the officials who promulgated them. This determination conflicts with decisions of this Court. Furthermore, this case is an ideal vehicle for considering the scope and nature of Federal jurisdiction to deal with this pervasive problem of testing, at the time they are officially proclaimed, regulatory requirements affecting every business enterprise within an entire industry. No facts are in dispute. No fact needed to decide the central legal issue will be any different in a future individual enforcement proceeding from the facts as they exist today. The challenged regulations were held invalid by the District Court before the Court of Appeals improperly declined on jurisdictional grounds to consider the matter.

1. On the basic question of justiciability, the issue as seen by both the District Court and the Court of Appeals was one of ripeness—may parties adversely affected by a regulation challenge its legality when it is promulgated or must they act at their peril and await the institution of penal or enforcement proceedings before the legality of the regulation can be judicially determined? In holding that the regulations at issue here were not ripe for review, the Court of Appeals has decided an important question of Federal law in a way that conflicts with decisions of this Court dealing with the review of administrative regulations,

Columbia Broadcasting System, Inc. v. *United States*, 316 U. S. 407 (1942); *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956); and *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956).

Columbia Broadcasting involved regulations of the FCC which provided that licenses would not thereafter be issued to stations having certain contractual relationships with networks. Even though, as the Court noted, the regulations were not self-executing—they "did not operate of their own force to deny or cancel a license," 316 U. S. at 417—the regulations were held to be ripe for review because of their adverse impact on CBS. The Court, moreover, specifically rejected two contentions accepted here by the Court of Appeals. First, this Court held that the regulations were reviewable even though it was not "certain" that enforcement proceedings would be instituted. 316 U. S. at 417-18. Compare pp. 7a-8a, *infra*.[6] Second, this Court rejected the

[6] The Court of Appeals' insistence that there be a specific threat of enforcement not only conflicts with *Columbia Broadcasting* and the other administrative law decisions of this Court—in none of which was there any such threat—it is also in conflict with this Court's decisions in cases in which the constitutionality of statutes is challenged in actions to enjoin their enforcement. In neither Truax v. Raich, 239 U. S. 33 (1915), nor Pierce v. Society of Sisters, 268 U. S. 510 (1925), for example, had there been an official threat or other governmental enforcement action of any kind when suit was instituted; in each case the threat existed by the nature of the statutory command or prohibition and its obvious viability, and in each case the impact of the challenged statutes upon the plaintiffs sufficed to present a justiciable controversy.

In this case, moreover, that petitioners had a "realistic fear of prosecution," see Poe v. Ullman, 367 U. S. 497, 508 (1961), and that the regulations themselves constituted a threat are confirmed by the position taken by respondents in the District Court when their counsel stated that enforcement proceedings would be instituted if the regulations were not complied with. (R. 24a, 36a). As the District Court observed, "Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means." P. 21a, *infra*.

contention that the regulations were reviewable only in an enforcement proceeding:

> "Having adopted this order under its rule-making power, the Commission cannot insist that [plaintiff] . . . be relegated to that judicial review which would be exclusive if the rule-making power had never been exercised and consequently never subjected [plaintiff] . . . to the threatened irreparable injury." 316 U. S. at 421. Compare p. 8a, *infra*.

Storer also involved a licensing regulation of the FCC. The regulation was held reviewable because "the Commission exercised a power of rule-making which controls broadcasters" and the regulations "now operate to control the business affairs of Storer," 351 U. S. at 199—conclusions directly applicable to the regulations at issue here.

This pragmatic approach to the question of ripeness was carried forward in *Frozen Food Express*, a case involving an interpretive report of the ICC in which it rendered its opinion as to the status of certain commodities under an exemption provided by the Interstate Commerce Act for the carriage of agricultural products by motor carriers. Over the contention that the report was not reviewable because it "has no operative effect," 351 U. S. at 46, a position adopted by the Court of Appeals here, pp. 5a, 7a, *infra*, this Court held that the report was reviewable because of its practical impact on carriers:

> "The determination by the Commission that a commodity is not an exempt agricultural product has an immediate and practical impact on carriers who are transporting the commodities . . . . The 'order' of the Commission warns every carrier, who does not have authority from the Commission to transport those commodities, that it does so at the risk of incurring criminal penalties. . . . Where unauthorized operations occur, the Commission may proceed adminis-

> tratively and issue a cease and desist order. . . . The determination made by the Commission is not therefore abstract, theoretical, or academic. . . . The 'order' of the Commission . . . is, indeed, the basis for carriers in ordering and arranging their affairs. . . . The 'order' of the Commission is in substance a 'declaratory' one . . . which touches vital interests of carriers . . . and sets the standard for shaping the manner in which an important segment of the trucking business will be done." 351 U. S. at 43-44.

Frozen Food Express thus plainly establishes, contrary to the Court of Appeals' determination here, that "interpretive" regulations are not *ipso facto* unreviewable.[7] Further, *Frozen Food Express* sets forth the standard for determining the ripeness of regulations for review, a standard that was met in this case, and demonstrates that no "abstract, theoretical, or academic" controversy was presented by these regulations. As in *Frozen Food Express*, the very existence of the regulations "has an immediate and practical impact on" petitioners. Compliance with the regulations requires petitioners to change their method of doing business. On the other hand, noncompliance with the "every time" requirement imposed by the regulations subjects petitioners to the risk of criminal penalties and seizure actions as well as adverse administrative actions. In sum, the petitioners here are in precisely the same situation as that which confronted the carriers in *Frozen Food Express*, and the holding there that a justiciable controversy was presented governs this case.

The Court of Appeals, however, refused to follow *Frozen Food Express* and the other controlling decisions of

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[7] In Lester C. Newton Trucking Co. v. United States, 209 F. Supp. 600, 602 (D. Del. 1962), *aff'd per curiam*, 372 U. S. 702 (1963), the three-judge court followed *Frozen Food Express* and held that an "interpretive opinion" of the ICC was reviewable.

this Court. The Court of Appeals sought to distinguish *Columbia Broadcasting* and *Frozen Food Express*—the Court did not mention the *Storer* case—on the ground that those cases arose under specific statutory review provisions and were not declaratory judgment actions. P. 4a, *infra*.[8] This purported distinction does not bear on the question of ripeness.

This Court has demonstrated that the rules governing justiciability are the same whether suit is brought under specific review provisions or the Declaratory Judgment Act. *Nukk* v. *Shaughnessy*, 350 U. S. 869 (1955), *reversing per curiam* 125 F. Supp. 498 (S. D. N. Y. 1954), was a declaratory judgment action brought to challenge the validity of administrative regulations, the same type of action as that involved here. The District Court held, as did the Court of Appeals here, that the regulations were not ripe for review because there had been no specific threat to enforce the regulations. This Court reversed *per curiam*, saying only:

> "The Court is of opinion that the complaints do present a case and controversy. *Rochester Telephone Corp.* v. *United States*, 307 U. S. 125. The judgment is reversed and the case is remanded for consideration on the merits." 350 U. S. at 869.

The *Rochester* case, although an action brought under a specific statutory review provision, was thus held dispositive in a declaratory judgment action.

The *Nukk* case, in which the Court thought the appropriate decision so clear that it need not even write a full opinion, is of course in accord with decisions of the Court

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[8] In fact, however, both *Frozen Food Express* and *Storer* were actions brought under the Administrative Procedure Act, as well as under the specific statutory provisions applicable to the ICC and FCC, respectively. See 351 U. S. at 42; 351 U. S. at 195.

in which it has spelled out its reasoning. The results reached in the *Columbia Broadcasting, Storer,* and *Frozen Food Express* cases mean that a challenge to a regulation that has an adverse effect on private parties produces a "case or controversy" in the constitutional sense; otherwise, despite the statutory review provisions, each of those cases should have been dismissed for lack of jurisdiction. As the Court has held, the requirement under the Declaratory Judgment Act that there be an "actual controversy" has the same meaning as the constitutional "case or controversy" requirement. *E.g., Public Serv. Comm'n* v. *Wycoff Co.,* 344 U. S. 237, 242 (1952); *United Pub. Workers* v. *Mitchell,* 330 U. S. 75, 89, 93 (1947). The decisions of this Court thus preclude the Court of Appeals' determination that no "actual controversy" existed under the Declaratory Judgment Act.

Furthermore, this case was brought under the Administrative Procedure Act as well as the Declaratory Judgment Act. Whatever may have been the situation prior to the enactment of the APA in 1946, it is now clear that under Section 10 of the APA "final agency action" is reviewable through declaratory judgment and injunction proceedings. See *Rusk* v. *Cort,* 369 U. S. 367, 375 (1962). It is also clear under the *Storer* case that the regulations at issue here constitute "final agency action" within the meaning of the APA. As has already been discussed, *Storer* was a case in which regulations were challenged upon their promulgation and, although a specific statutory review provision was involved in that case, the action was also brought under the APA. The Court held that the regulations were reviewable under the APA:

> "We think respondent had standing to sue at the time it exercised its privilege. The process of rule making was complete. It was final agency action, 5 U.S.C. § 1001(c) and (g) . . ." 351 U. S. at 198.

Here, too, "the process of rulemaking was complete" when the complaint was filed in the District Court. Here, too, the issuance of the regulations by the respondents constituted "final agency action" within the meaning of Section 10 of the APA.[9] It is thus untenable to suggest, as the Court of Appeals held, that the leading administrative law decisions of this Court have no bearing on actions brought under the APA and the Declaratory Judgment Act to challenge administrative regulations.[10]

At the risk of belaboring the obvious, it should be pointed out that Professors Jaffe and Davis, two renowned

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[9]The implication in the Court of Appeals' opinion, p. 5a, *infra*, that the regulations at issue here are not within § 10 of the APA is inexplicable in light of the definition of "agency action" in § 2(g) of the APA, 60 Stat. 238 (1946), 5 U.S.C. § 1001(g), as including "every agency rule . . . ." "Rule" is defined in § 2(c) of the APA, 60 Stat. 237 (1946), 5 U.S.C. § 1001(c), as "any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," a definition which clearly encompasses the regulations at issue in this proceeding.

[10]This Court's decisions in Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950), and Whitney Nat'l Bank v. Bank of New Orleans, 379 U. S. 411 (1965), relied on by the Court of Appeals, do not affect the *Columbia Broadcasting* line of cases which govern this action. *Ewing* involved an attempt to review a finding of probable cause, not a final regulation. *Whitney Nat'l Bank* rested on the fact that the appropriate agency had never passed upon the contentions urged in the courts; here, petitioners' position as to the illegality of the "every time" requirement had been presented to and rejected by the respondents before this action was filed in the District Court. See n.3, *supra*.

Similarly, although the Court of Appeals stated that Helco Prods. Co. v. McNutt, 137 F. 2d 681 (D. C. Cir. 1943), was perhaps "the closest parallel" to this case, p. 8a, *infra*, *Helco* involved an informal, unpublished letter of the Food and Drug Administration, not formal and purportedly final and effective regulations.

The Court of Appeals' reliance on the provision in § 502(e)(1)(B) for exemptions from the requirements of that section where compliance would be "impracticable" was also misplaced, for in *Storer* this

students of administrative law, have independently recognized the applicability to declaratory judgment actions of the principles announced in cases brought under specific review provisions. Jaffe, *Ripeness and Reviewable Orders in Administrative Law*, 61 Mich. L. Rev. 1273, 1286-87 (1963); 3 Davis, *Administrative Law* § 21.06, at 150-51 (1958). In the words of Professor Davis:

> "In many cases, regulations of the ICC and of the FCC have been challenged by suits for injunctions under the Urgent Deficiencies Act; if a suit under that Act is not premature, no reason is apparent for holding premature an ordinary bill in equity or a declaratory action." *Ibid.* (Footnotes omitted.)[11]

The Court of Appeals' decision can be read as resting in considerable part on the fact that Congress provided for review in the Courts of Appeals of Food and Drug Administration regulations issued under certain provisions of the Act, not including those pursuant to which the regu-

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Court held a regulation reviewable even though the FCC could waive its requirements. See 351 U. S. at 205. Furthermore, the exemption provision applies only to the section of the regulations dealing with labels and labeling and not to the section dealing with advertising, and, finally, petitioners' contention is that the regulations, whether or not compliance would be "practicable," are invalid.

[11]Professor Davis, moreover, specifically mentions the "sound holding" in Toilet Goods Ass'n v. Celebrezze, 235 F. Supp. 648 (S. D. N. Y. 1964), that other regulations issued by these respondents may be challenged in a declaratory judgment action in a District Court. 3 Davis, *Administrative Law* § 21.08, at 45 (Supp. 1965). District Judge Tyler in the *Toilet Goods* case relied heavily on the opinion of the District Court in this case.

After the Court of Appeals' decision in this proceeding, these respondents renewed their motion to dismiss in the *Toilet Goods* case. On December 6, 1965, Judge Tyler reaffirmed his prior ruling that a justiciable controversy was presented and again denied the motion; he has authorized an interlocutory appeal from his action to the Court of Appeals for the Second Circuit under 28 U. S. C. § 1292(b).

lations here were issued, and that therefore Congress meant to preclude review of other FDA regulations.

It should be emphasized, however, that there is no question of reviewability *vel non* presented in this case. As the Court of Appeals itself recognized, p. 8a, *infra*, the validity of the regulations can be determined by a District Court in an enforcement action. Thus, the question is one of ripeness —when, and not whether, the regulations are reviewable— a question which is controlled by the *Columbia Broadcasting* line of cases.

Moreover, to the extent that the decision below is based on an assumed congressional intent to preclude review, it conflicts with this Court's decisions in *Leedom* v. *Kyne*, 358 U. S. 184 (1958), and *Rusk* v. *Cort*, 369 U. S. 367 (1962).

In *Leedom* v. *Kyne* this Court affirmed a judgment of a District Court granting an injunction setting aside an order of the National Labor Relations Board that was not among the kinds of NLRB orders made reviewable by statute in the Courts of Appeals. The members of the Board, named individually as defendants in the District Court suit, conceded in this Court that the District Court had jurisdiction "unless the review provisions of the National Labor Relations Act destroyed it." 358 U. S. at 187. Contrary to the holding of the Court below with respect to the review provisions of the Food, Drug, and Cosmetic Act, this Court held that the specification by Congress of certain NLRB orders as being reviewable in the Courts of Appeals did not by negative implication destroy equitable district-court jurisdiction of suits challenging other kinds of orders.

Decisions of other Courts of Appeals sanctioning district-court suits challenging agency actions not among those made reviewable by the Courts of Appeals are in accord

with *Leedom* v. *Kyne* and equally in conflict with the decision below. *Elmo Division of Drive-X Co.* v. *Dixon*, 348 F.2d 342, 343 (D. C. Cir. 1965) ("Statutory provisions concerning review of agency action by the Courts of Appeals do not in and of themselves . . . preclude District Court jurisdiction"); *Deering Milliken, Inc.* v. *Johnston*, 295 F. 2d 856 (4th Cir. 1961).

In *Leedom* v. *Kyne* the District Court's jurisdiction was founded on 28 U. S. C. § 1337, the statute giving the District Courts jurisdiction of cases arising under acts regulating commerce. In *Rusk* v. *Cort*, an action was brought under Section 10 of the Administrative Procedure Act and the Declaratory Judgment Act by a person located outside the United States who claimed that he had been illegally denied a passport. The Immigration Act specifically authorized declaratory actions by persons located within the United States to challenge the withholding of passports, and it set forth a procedure whereby persons outside the United States could challenge such denials in habeas corpus proceedings. This Court nevertheless held that the APA permitted the institution of declaratory judgment actions by persons not located within the United States. The Court noted the "broad provisions" of the APA and the Declaratory Judgment Act, 369 U. S. at 372, stated that "the Administrative Procedure Act confers the right to judicial review of 'any agency action'," 369 U. S. at 375, and, referring to *Shaughnessy* v. *Pedreiro*, 349 U. S. 48 (1955), and *Brownell* v. *Tom We Shung*, 352 U. S. 180 (1956),[12] concluded:

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[12] The Court in *Shaughnessy* v. *Pedreiro* referred to "the generous review provisions" of the APA and said that they granted "an expanded right of review" and that the APA "is to be given a 'hospitable' interpretation." 349 U. S. at 51. *Brownell* v. *Tom We Shung* also mentions the "expanded mode of review" granted by the APA. 352 U. S. at 185.

> "[T]he Court will not hold that the broadly remedial provisions of the Administrative Procedure Act are unavailable to review administrative decisions under the 1952 [Immigration] Act in the absence of clear and convincing evidence that Congress so intended." 369 U. S. at 379-80.[13]

In short, the Court held in *Leedom* v. *Kyne* and *Rusk* v. *Cort* that statutory provisions authorizing review of certain orders, in the first case, or review by a certain class of persons, in the latter, were not "clear and convincing evidence" that Congress intended to preclude review of other orders or by other persons. The Court of Appeals here, however, reached precisely the opposite conclusion, holding that because certain types of regulations were made specifically reviewable, Congress did not intend judicial review of the regulations at issue in this case.[14]

2. Even if it should be thought that the Court of Appeals' decision does not conflict with decisions of this Court,

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[13]That a strong showing must be made in order to preclude review under the APA is also demonstrated by Schilling v. Rogers, 363 U. S. 666 (1960). Four members of the Court there would have held that the APA was available to review an administrative determination under the Trading with the Enemy Act even though the Act specifically stated that the remedies provided in the Act, which did not include any provision for judicial review so far as the plaintiff there was concerned, shall be "the sole relief and remedy" of claimants of vested property. §7(c), 40 Stat. 1021 (1918), 50 U.S.C. App. §7(c). There is, of course, no such provision in the Food, Drug, and Cosmetic Act.

[14]Indeed, this case is a stronger one for reviewability than *Rusk* v. *Cort*, where there was some legislative history which the dissenting opinion read as reflecting a congressional intent to preclude review. Here, on the other hand, the Court of Appeals did not cite any legislative history material at all to show that Congress even considered precluding review of regulations of the type involved in this proceeding.

it clearly cannot be contended that that decision was compelled by any decision of this Court. Review by this Court is warranted so that the important questions presented can be definitively settled.

This case was brought by the prescription drug industry in order to obtain a prompt judicial determination as to whether there must be compliance with regulations that the industry believed were without statutory basis. The decision of the District Court holding the regulations invalid demonstrates that, at the very least, the industry's belief was and is based on substantial grounds. The alternative to this action—and the result of the Court of Appeals' decision if not reversed—would be a multitude of enforcement proceedings against individual companies which do not comply with the regulations, an alternative which not only leads to unnecessary litigation but which resolves only in piecemeal fashion the question whether the regulations are lawful.

The issue is tendered on cross-motions for summary judgment. It should be resolved. There is no justification for allowing the respondents to hold an industry at hazard under illegal regulations while they sit back, attack particular companies for noncompliance when the occasion seems right, letting others who do not comply go unchallenged, and use all the pressures at their command to force compliance with illegal regulations as the price of administrative authorizations needed to do business.

The public interest would certainly not be served by further delay and uncertainty. As Professor Jaffe has said:

> "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan, or not to plan, his operation on the basis of a regulation." Jaffe, *supra*, 61 Mich. L. Rev. at 1283.

Or, in the words of a perceptive District Judge who held other regulations issued by these respondents to be reviewable in a declaratory judgment action:

> "[T]o resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and inefficient, not only for the plaintiffs but as well for the public as represented by the defendants." *Toilet Goods Ass'n* v. *Celebrezze*, 235 F. Supp. 648, 651 (S. D. N. Y. 1964). See also *National Van Lines, Inc.* v. *United States*, 326 F. 2d 362, 373 (7th Cir. 1964); *ICC* v. *Atlantic Coast Line R. R.*, 334 F. 2d 46, 51 (5th Cir. 1964), *cert. granted*, 379 U. S. 957 (1965).

Indeed, as stated by one of the respondents in this proceeding:

> "When any interested party feels that one of our regulations is wrong and should be challenged in the courts, we welcome such an action. Court decisions interpreting sections of the law or regulations that have given rise to honest differences of opinion are most helpful to us as guidelines to fair administration." Address of Commissioner George P. Larrick before the Pharmaceutical Manufacturers Association, April 14, 1964, p. 4.

II

The second question presented relates to where actions against Federal officials may be brought. Section 1391(e)(4) of Title 28, enacted in 1962 to liberalize venue requirements for actions against Federal officials,[15] provides that such actions may be brought in any district in

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[15] See S. Rep. No. 1992, 87th Cong., 2d Sess. 2 (1962); H.R. Rep. No. 536, 87th Cong., 1st Sess. 1-2 (1961). The previous venue provisions had resulted in actions against Federal officials being concentrated in the District Court for the District of Columbia, and Section 1391(e) was designed to lessen the burden on that Court by permitting such actions to be brought in courts throughout the country. See S. Rep. No. 1992, *supra*, at 3; H.R. Rep. No. 536, *supra*, at 3.

which "the plaintiff resides . . . ." Petitioners contended that the definition of corporate residence in 28 U.S.C. § 1391(c)—where a corporation is incorporated, licensed to do business or doing business—should be incorporated into the word "resides" in Section 1391(e)(4).[16] The District Court rejected this contention and held that venue was improper as to those petitioners not incorporated in Delaware, and the Court of Appeals affirmed the dismissal of the complaint as to such petitioners. The District Court relied on cases dealing with an analogous question—whether the definition of corporate residence in Section 1391(c) applies to corporate plaintiffs in cases where venue is governed by 28 U. S. C. § 1391(a) —, a question on which, as the District Court noted, p. 15a, *infra*, there is "a classic split of authority" among the lower Federal courts[17] and the commentators.[18] Judge Wright observed:

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[16]The Court so held in Toilet Goods Ass'n v. Celebrezze, 235 F. Supp. 648 (S. D. N. Y. 1964), the only other case arising under Section 1391(e) in which this question has been presented.

[17]*Compare* Freiday v. Cowdin, 83 F. Supp. 516, 517-18 (S. D. N. Y. 1949), *appeal dismissed by consent*, 177 F. 2d 1020 (2d Cir. 1949); Hadden v. Barrow, Wade, Guthrie & Co., 105 F. Supp. 530 (N. D. Ohio 1952); Southern Paperboard Corp. v. United States, 127 F. Supp. 649 (S. D. N. Y. 1955); Eastern Motor Express, Inc. v. Espenshade, 138 F. Supp. 426, 431 (E. D. Pa. 1956); Standard Ins. Co. v. Isbell, 143 F. Supp. 910 (E. D. Tex. 1956); Travelers Ins. Co. v. Williams, 164 F. Supp. 566 (W. D. N. C. 1958); Wear-Ever Aluminum, Inc. v. Sipos, 184 F. Supp. 364 (S. D. N. Y. 1960); and Consolidated Sun Ray, Inc. v. Steel Ins. Co. of America, 190 F. Supp. 171 (E. D. Pa. 1961), *with* Robert E. Lee & Co. v. Veatch, 301 F. 2d 434 (4th Cir. 1961), *cert. denied*, 371 U. S. 813 (1962); Carter-Beveridge Drilling Co. v. Hughes, 323 F. 2d 417 (5th Cir. 1963); Chicago & North Western Ry. v. Davenport, 94 F. Supp. 83 (S. D. Iowa 1950); United Merchants & Mfrs., Inc. v. United States, 123 F. Supp. 435 (M. D. Ga. 1954) (dictum); Albright & Friel, Inc. v. United States, 142 F. Supp. 607 (E. D. Pa. 1956); Nebraska-Iowa Bridge Corp. v. United States, 158 F. Supp. 796 (D. Neb. 1958); and North River Ins. Co. v. Davis, 237 F. Supp. 187 (W. D. Va. 1965).

[18]*Compare* Wright, *Federal Courts* § 42, at 132-33 (1963); 76 Harv. L. Rev. 641 (1963); 1 Barron & Holtzoff, *Federal Practice & Procedure* § 80, at 387-88 (rev. ed. 1960), § 80, at 180 (Supp.

> "Because of the well-balanced forces of reason on either side of this controversy a gentlemanly disagreement will no doubt continue among the courts and commentators until settled by Congress or the Supreme Court." P. 18a, *infra*.

The venue question presented in this case, an issue of statutory construction unaffected by differing circumstances of different cases, is a question of basic importance involving the situs of cases dealing with the legality of actions of Federal officials. It is a question on which the guidance of this Court is needed.

1965), citing Note, 28 Ind. L. J. 256 (1953), and Note, 37 Ind. L. J. 363 (1962); Wechsler, *Federal Jurisdiction and the Revision of the Judicial Code*, 13 Law & Contemp. Prob. 216, 240 n.126 (1948); and Note, 60 Harv. L. Rev. 424, 434-35 (1947), *with* 48 Va. L. Rev. 968 (1962); Comment, 28 U. Chi. L. Rev. 112 (1960); 1 Moore, *Federal Practice* ¶ 0.142 [5.-3], at 1503 (2d ed. 1950); 1-A Ohlinger, *Federal Practice* ¶ 2.3.4, at 297 (1950).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15055

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS,

Appellants

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Argued April 2, 1965

Before: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

OPINION OF THE COURT

(Filed November 1, 1965)

By WEBER, *District Judge*

This is an appeal from a declaratory judgment and injunction granted to plaintiffs in the District Court which holds that regulations issued and promulgated by defendants, the Secretary of Health, Education and Welfare, and the Commissioner of Food and Drugs are null and void and not authorized by the statute on which they are based. The injunction restrains the defendants and all parties acting under them from enforcing or attempting to enforce the regulations.

The statute involved is popularly known as the "Drug Amendments of 1962", which added the provisions in question to the Federal Food, Drug and Cosmetic Act, as amended. 21 U.S.C. § 301 et seq. (The Act).

§ 502 (e) (1) (B) of the Act, 21 U.S.C. 352 (e) (1) (B) provided that the labeling of a prescription drug shall be considered "misbranded" unless the established or generic name of the drug is printed prominently on the label in type half as large as any brand or proprietary name. § 502 (n) of the Act contains a similar requirement for advertising matter concerning the drug. Penalties are provided for "misbranding."

The generic name or the established name of a drug is its chemical name, a common name, or an official name used in an official compendium. The proprietary name is the name given by the manufacturer to designate its source of manufacture and to differentiate its product from the same or chemically similar drugs from other manufacturers.

§ 502 (e) (1) (B), 21 U.S.C. 352 (e) (1) (B) contains a provision that to the extent that compliance with the requirements is impracticable, exceptions shall be established by regulations promulgated by the Secretary.

§ 701 (a), 21 U.S.C. 371 (a) grants the authority to the Secretary to promulgate regulations for the efficient enforcement of the Act, except as otherwise provided in that section.

§ 701 (e) (1) of the Act provides the procedure to be employed for the issuance, amendment, or repeal of any regulations under specific sections of the Act, including the filing and disposition of objections thereto by full hearing, the issuance of final orders thereon by the Secretary, and the provision for appeal thereon to the Circuit Court of Appeals. The sections of the Act in question here were not covered by the hearing appeal process recited above.

Pursuant to the authority to promulgate regulations, the Commissioner, as the delegate of the Secretary, issued the regulations in question here, which provided that under the provisions of § 502 (e)(1)(B), (the labeling requirement), and § 502 (n), (the advertising requirement) of the Act, *each time* the trade name is used on labels or labeling, or in advertisements of prescription drugs, the established name shall also be used prominently and in type half as large. (21 C.F.R. 1.104 (g)(1) and 1.105 (b)(1); 28 Fed. Reg. 6375 and 6376). These regulations were adopted in accordance with the procedure provided by § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, after publication of notice of intent, and the submission of comments and objections by interested parties.

Plaintiffs brought this action in the District Court praying for declaratory judgment and injunctive relief. They rely on the existence of a Federal question, 28 U.S.C. 1331, the Declaratory Judgment Act, 28 U.S.C. 2201, and § 10 of the Administrative Procedure Act, 5 U.S.C. 1009 for jurisdiction. They contend that the *each time* requirements of the regulations are invalid as beyond the requirements of the Act.

The District Court found it unnecessary to rule whether § 10 of the Administrative Procedure Act provided a basis for review of the regulations. It took cognizance of the case under the Declaratory Judgment Act on the grounds that the regulations placed plaintiffs in a position of peril and imminent danger, and that the regulations in question were ripe for review. It not only declared the regulations void because the statute would not bear the interpretation placed upon it, but also issued a sweeping injunction against the enforcement thereof.

Questions of venue of the District Court for all of the many plaintiffs, the standing of a trade association as a party, the inclusion of the Attorney General as a necessary party, and the status of the case as an unconsented suit against the United States were disposed of by the Court,

and by reason of the conclusions reached herein, will not be discussed.

The basic question on appeal here is one of justiciability. May the district court review, under the Declaratory Judgment Act, an interpretive regulation of the Commission issued under authority of the statute, where Congress has not provided for judicial review of the sections in question? Furthermore, was such review within the statutory scheme of regulation imposed by Congress when it specifically provided for judicial review of other regulations authorized under certain specific sections of the Act, as set forth in §10 (e)(1), 21 U. S. C. 371? We believe that the answer would be the same under the provisions of § 10 of the Administrative Procedure Act, which imposes essentially the same requirements for justiciability as the Declaratory Judgment Act.

A District Court of the United States is limited to those cases over which Congress has granted it jurisdiction. To a large extent the provisions for judicial review of administrative agency action are not applicable to the District Courts, but are placed under the jurisdiction of the Courts of Appeal. Those cases arising from the District Courts which review administrative regulations are largely based on statutory provisions for such review. *Frozen Food Express Co. v. United States*, 351 U. S. 40 (1956), was reviewed under the statutory scheme for review of I.C.C. orders by a specially constituted District Court, 28 U.S.C. 1336. *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407 (1942) arose under § 402 (a) of the Communications Act of 1934, 47 U.S.C. § 402 (a), which provided for judicial review of certain orders of the Federal Communications Commission by a specially constituted District Court, with direct appeal therefrom to the Supreme Court. Under § 402 (b) of that Act review of other types of orders are available only through an appeal to the Court of Appeals of the District of Columbia.

It seems clear to this Court that the intent of Congress was that the administrative regulations for which no review was specifically provided prior to enforcement were those interpretive regulations which represented the Commissioner's interpretation of the meaning of the Act. The regulations in question are not those having the force and effect of law by virtue of authority delegated by the Act; they are not an "adjudication" and they are not an "order" and "licensing" under the definitions of § 2 (d) of the Administrative Procedure Act, 5 U.S.C. 1001 (d), as a standard for determination of final agency action as required for judicial review under § 10 of that Act.

The regulations in question were adopted pursuant to § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, which provided for a hearing on the proposed rules before their promulgation. In such a case, the intent of Congress as shown by the specific review provisions of the Act, 21 U.S.C. 371 (e), was to preclude judicial review prior to the enforcement stage. It may be noted that in § 502 (e) (1) (B), Congress has provided for exemption regulations for the labeling requirements where compliance is impracticable. No attempt has been made by plaintiffs to secure relief under that provision.

It has been frequently held that judicial review of such preliminary administrative determination does not fit the statutory scheme of Congress. As was stated in *Ewing v. Mytinger & Casselberry*, 339 U. S. 594 (1950), at p. 600-601:

> "Congress made numerous administrative determinations under the Act[1] reviewable by the Courts[2]. But it did not place the finding of probable cause under § 304 (a) in that category. This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was

[1]The Act in question here.
[2]Foot-note omitted.

the one provided for in the libel suit. Cf. *Switchmen's Union v. Board*, 320 U. S. 297, 305-306.".

As has been recently stated by the Supreme Court in *Whitney National Bank v. Bank of New Orleans*, 379 U. S. 411 (1965) at p. 420:

> "Congress has set out in the Bank Holding Company Act of 1956 a carefully planned and comprehensive method for challenging Board determinations. That action by Congress was designed to permit an agency, expert in banking matters, to explore and pass on the ramifications of a proposed bank holding company arrangement. To permit a district court to make the initial determination of a plan's propriety would substantially decrease the effectiveness of the statutory design."

and at page 422:

> "That Congress has not expressly provided that the statutory procedure is to be exclusive does not require a different conclusion."

In addition to the policy of Congress in limiting the administrative matters for which judicial review was provided, which did not include the sections of the Act in question, there are serious obstacles to the use of the Declaratory Judgment Act here as a basis of jurisdiction.

> "A declaratory judgment, like other forms of equitable relief, should be granted only as a matter of judicial discretion, exercised in the public interest. *Brillhart v. Excess Insurance Co.*, 316 U. S. 491; *Great Lakes Dredge & Dock Co. v. Huffman*, 319 U. S. 293, 297-98; H. R. Rep. No. 1264, 73rd Cong. 2d Sess. p. 2; Borchard, Declaratory Judgments (2d ed. 1941) pp. 312-14. It is always the duty of a court of equity to strike a proper balance between the needs of the plaintiff and the consequences of giving the desired relief. Especially where government action is involved, courts

should not intervene unless the need for equitable relief is clear, not remote or speculative." *Eccles v. Peoples Bank*, 333 U. S. 426, at p. 431 (1948).

The regulations in question are advisory statements as opposed to legislative rules. Cf. *Standard Scale Co. v. Farrell*, 249 U. S. 571 (1919). The Act does not give them the force of law, they rise no higher than the terms of the Act itself.

The Declaratory Judgment Act confines the remedy to be limited to an actual "case or controversy". There must be proof of threatened enforcement action that would cause irreparable harm; the judgment sought must conclusively settle a specific controversy between the parties. *Public Service Comm'n v. Wycoff*, 344 U. S. 237 (1952).

The case must be appropriate for judicial determination. The relief is available only for a "concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged . . . ." *Aetna Life Insurance Co. v. Haworth*, 300 U. S. 227, 241 (1937).

In the case in question the district court was asked for an advisory opinion rather than a concrete decision. It was asked to substitute its discretion for an administrative discretion as to the meaning of the Act. No specific case was presented, no immediate prosecution threatened. The administrative intention was expressed but had not yet come to fruition.

"The judicial power does not extend to the determination of abstract questions. *Muskrat v. United States*, 219 U. S. 346, 361; *Liberty Warehouse Co. v. Grannis*, 273 U. S. 70, 74; *Willing v. Chicago Auditorium Assn.*, 277 U. S. 274, 289; *Nashville, C. & St. L. Ry. Co. v. Wallace*, 288 U. S. 249, 262, 264." *Ashwander v. Tennessee Valley Authority*, 297 U. S. 288, at p. 324 (1936)

The threat of enforcement must be real, and not merely implied by the existence of the law and regulations. This would require the exercise of administrative discretion by the agency and also by the Attorney General. There was no threat of enforcement facing the plaintiffs here sufficient to give an adequate basis for declaratory relief. *United Public Workers v. Mitchell*, 330 U.S. 75, (1946).

Perhaps, the closest parallel to the instant case is *Helco Products Co. v. McNutt*, 137 F.2d 681 (D. C. Cir. 1943), which involved an administrative interpretation of a section of the same Act by the Commissioner. The Court details the stages of exercise of discretion between an administrative interpretation and prosecution. The Court concluded at p. 683:

> "We conclude that the present case was not an appropriate one for declaratory judgment . . . The Supreme Court has said the pronouncements, policies and programs of a government administrative agency do not give rise to a justiciable controversy, save as they have fruition in action of a definite and concrete character, constituting an actual or threatened interference with the rights of persons complaining." (citing *Ashwander v. T.V.A.*, supra).

The jurisdiction of the District Court in this case is likewise limited by equitable principles that such relief as is demanded here is available only in the absence of an adequate remedy at law. *Beacon Theatres v. Westover*, 359 U.S. 500, (1958), *Douglas v. Jeannette*, 319 U.S. 157 (1943). Congress has provided a variety of avenues of legal remedy; the exemption provision in the statute where compliance is impracticable, the opportunity to be heard in the rule making proceedings of § 4 of the Administrative Procedure Act; the opportunity to test the interpretation under the enforcement procedures provided for "misbranding", which are (1) seizure proceedings, (2) injunction proceedings, or (3) criminal prosecution. § 301 (a) and (b), 21 U.S.C. 331 (a) and (b). Likewise, if enforcement should be attempted under the new drug clearance procedures of § 505, 21 U.S.C. 355, or the antibiotic certification, § 507, 21 U.S.C. 357, there are

provisions for administrative hearing and review by the Court of Appeals. Ultimately, final recourse to the District Court for relief under the Declaratory Judgment Act or the Administrative Procedure Act, § 10 in a concrete factual setting involving an actual controversy, is not ruled out at a later stage in the administrative process.

We, therefore, hold that in view of the policy of Congress limiting prior judicial review of administrative actions under this Act to specific sections, not including the ones in question, and in view of the absence of an "actual case or controversy" required for justiciability under the Declaratory Judgment Act, the action of the district court was beyond its permissible area of discretion and the judgment must be vacated, the injunction dissolved, and the action dismissed.

An appropriate order will be entered.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15054

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U. S. A.) INC.; CARTER PRODUCTS, INC.; HOFFMAN-LA ROCHE, INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; [redacted]. H. ROBINS COMPANY, INCORPORATED; [redacted]OWELL LABORATORIES, INC.; SCHERING CORPORATION; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES,

Appellants

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Argued April 2, 1965

Before HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

OPINION OF THE COURT

(Filed November 1, 1965)

PER CURIAM.

The named appellants in the above entitled case are some, but not all, of the plaintiffs who joined in the complaint for declaratory judgment and injunctive relief.

We find no prejudicial error in the dismissal of the complaint as to these plaintiffs, and that action will be affirmed.

APPENDIX C

IN THE

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Civil Action No. 2737

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMERICAN HOME PRODUCTS CORPORATION; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BAXTER LABORATORIES, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U.S.A.) INC.; CARTER PRODUCTS, INC.; CUTTER LABORATORIES; THE DOW CHEMICAL COMPANY; HOFFMAN-LAROCHE INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; CHAS. PFIZER & CO., INC.; PHILIPS ROXANE, INC.; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; G. D. SEARLE & CO.; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES; STERLING DRUG, INC.; THE UPJOHN COMPANY; VALE CHEMICAL COMPANY, INC.; WARNER-LAMBERT PHARMACEUTICAL COMPANY; PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

Plaintiffs,

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and

GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS,

Defendants.

OPINION

WRIGHT, *Chief Judge.*

This action arises under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended 21 U.S.C. § 301, et seq. ("the Act").

According to § 502(e)(1)(B) of the Act, 21 U.S.C. § 352(e)(1)(B), the labeling of a prescription drug shall cause that drug to be "misbranded" unless the established or generic name of the drug is printed prominently on any label or labeling material, as defined in the Act, in type half as large as any brand or proprietary name.[1]

The proprietary, or brand name, of a prescription drug is used by the manufacturer to identify the source of the drug. The proprietary name distinguishes the drug manufactured by one company from the drug with active ingredients of the same or similar chemical constitution produced by another company. Thus a physician can, if he desires, exercise a choice among sources in prescribing drugs for his patient.

Most prescription drugs also have a non-proprietary or generic name. Such a name may be a systematic chemical name, a common name, or an official name used in some official compendium or designated by the Secretary of Health, Education and Welfare. This is the "established name" which § 502(e)(1)(B) requires to be prominently displayed on drug labeling. If this requirement is not met and a misbranded drug is introduced into interstate commerce (a) the drugs may be seized and forfeited, (b) the introduction of such drugs into interstate commerce may be enjoined, (c) the persons who cause introduction of the misbranded

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[1]The language of § 502(n) of the Act, 21 U.S.C. § 352(n) which applies to advertising is similar. This opinion covers both sections although only § 502(e) is specifically discussed.

drugs into interstate commerce may be subject to criminal prosecution.

In February, 1963, the defendant, Commissioner of Food and Drugs proposed the adoption of certain new regulations under the Act. The final regulations, 28 Fed. Reg. 6375, were promulgated in June, 1963 and were effective on publication. It is these regulations which are under attack in the present proceeding. Under the new regulations the Act is interpreted to require that the established or generic name be placed in conjunction with every appearance of the proprietary name of the drug on labels and advertising.

Thirty-seven drug companies and the Pharmaceutical Manufacturers Association (PMA) have joined as plaintiffs to challenge the every time requirement. They claim that the statute does not direct or authorize the defendant Commissioner to impose the requirement and that the Commissioner's regulations are therefore null and void. They seek a declaratory judgment to that effect and an injunction restraining defendants from enforcing the disputed regulation. The plaintiffs assert that in the absence of such relief they will be forced to choose between flouting the regulation and possibly incurring penalties or reprinting great quantities of advertising material which already complies with the statute as plaintiffs interpret it. This material, including brochures, price lists, catalogues, and labels prominently sets forth the generic name of the prescription drug involved but it does not meet the every time requirement.

At the outset, a host of jurisdictional problems are presented.

I. Venue

The defendants, Secretary of Health, Education and Welfare and Commissioner of Food and Drugs claim that venue is improper as to twenty-six of the thirty-seven plaintiff corporations. These twenty-six are not incorporated in the State of Delaware.

The applicable venue statute, 28 U.S.C. 1391(e) reads:

> "A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action."

Defendants admit that the pharmaceutical companies incorporated in Delaware are residents of Delaware within 28 U.S.C. 1391(e)(4). They maintain that the other plaintiffs fall without the bounds of the venue provision because they do not reside in the forum state.

28 U.S.C. 1391(e) does not define residence as applied to corporations. Elsewhere in the venue statute, however, at 28 U.S.C. 1391(c) it is provided:

> "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes."

Plaintiffs argue that this broad definition of residence should be applied to the twenty-six contested parties. Defendant counters that 28 U.S.C. 1391(c) applies only to corporations appearing as defendants and not to plaintiff corporations because it refers only to corporations which "may be sued."

The interpretation of 28 U.S.C. 1391(c) presents no novel question. There is a classic split of authority among the federal courts as to whether the statute applies to defendant corporations only or to plaintiff and defendant

corporations alike.[5] Nor do the commentators find ground for agreement.[6]

Those courts which conclude that 28 U.S.C. 1391(c) redefined the law of corporate residence for corporations as plaintiffs as well as corporations as defendants rely on

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[5]Defendant corporations only:

Chicago & North Western Ry. Co. v. Davenport, 94 F. Supp. 83 (S.D. Iowa 1950); United Merchants & Manufacturers Inc. v. United States, 123 F. Supp. 435 (M.D. Ga. 1954) [Dicta]; Albright & Friel, Inc. of Delaware v. United States, 142 F. Supp. 607 (E.D. Pa. 1956); Nebraska-Iowa Bridge Corporation v. United States, 158 F. Supp. 796 (D. Neb. 1958); Robert E. Lee & Co. v. Veatch, 301 F.2d 434 (4 Cir. 1961) cert. den. 371 U.S. 813 (1962).

Plaintiff and defendant corporations:

Freiday v. Cowdin, 83 F. Supp. 516 (S.D.N.Y. 1949); Hadden v. Barrow, Wade, Guthrie & Co., 105 F. Supp. 530 (N.D. Ohio 1952); Southern Paperboard Corporation v. United States, 127 F. Supp. 649 (S.D.N.Y. 1955); Eastern Motor Express, Inc. v. Espenshade, 138 F. Supp. 426 (E.D. Pa. 1956); Standard Insurance Company v. Isbell, 143 F. Supp. 910 (E.D. Tex. 1956); Travelers Insurance Company v. Williams, 164 F. Supp. 566 (W.D.N.C. 1958) aff'd. 265 F.2d 531 (4 Cir. 1959); Wear-Ever Aluminum, Inc. v. Sipos, 184 F. Supp. 364 (S. D. N. Y. 1960); Consolidated Sun Ray, Inc. v. Steel Insurance Company of America, 190 F. Supp. 171 (E.D. Pa. 1961).

[6]Defendant corporations only:

1 Moore, Federal Practice 1503 (2d ed. 1950); Ohlinger's Federal Practice (Rev. ed.) Vol. 1-A, p. 297; Comment, "The Corporate Plaintiff and Venue under Section 1391(c) of the Judicial Code, 28 Univ. Chi. L. Rev. 112 (1960); Case note, 48 Va. L. Rev. 968 (1962).

Plaintiff and defendant corporations:

Wright, Federal Courts, § 42 (1963); Wechsler, Federal Jurisdiction and the Revision of the Judicial Code, 13 Law & Contemporary Problems 216, 240 note 126; Note, The Proposed Revision of the Federal Judicial Code, 60 Harv. L. Rev. 424 (1947); Case note, 76 Harv. L. Rev. 641 (1963); 1 Barron and Holtzoff, Federal Practice and Procedure, 387-88 (Rev. ed. 1960) citing note, Federal Venue and the Corporate Plaintiff: Judicial Code § 1391(c); 28 Ind. L. J. 256 (1953) and note, Federal Venue and the Corporate Plaintiff, 37 Ind. L. J. 363 (1962).

interpretation of the last words of the section, "and such judicial district shall be regarded as the residence of such corporation for venue purposes." These words, it is argued, would be superfluous unless applied to corporations as plaintiffs, for the first part of the section grants the right to sue corporations as defendants where they are incorporated, or licensed to do business, or are actually doing business.

Judge Dimock's statement is representative:

> "I do not feel at liberty to attribute to Congress any * * * tautology. The statute first gives permission to sue a corporation in any district where it is incorporated or licensed or doing business. It then declares that such district shall be regarded as its residence. No one has suggested any reason for that declaration unless it was to give permission to the corporation to sue others in such district in addition to the previously given permission given to others to sue the corporation in any such district." Southern Paperboard Corporation v. United States, 127 F. Supp. 649, 650 (S.D. N.Y. 1955).

Professor Moore has found a meaning for the disputed words which does not comport with the above.

> "The language of the first clause of subsection (c) restricts the subsection to a corporation which 'may be sued.' And this restriction does not make superfluous the second, and concluding clause that 'such judicial district [in which the corporation is incorporated or licensed to do business or is doing business] shall be regarded as the residence of such corporation for venue purposes.' This clause serves a purpose in laying venue, in a transitory action, in a defendant's district where there are multiple defendants residing in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state. * * *" 1 Moore, Federal Practice 1503 (2d ed. 1963).

Nonetheless, Moore does not place his chief reliance on this interpretation in deciding that the statute defines residence for corporate defendants only. He emphasizes the fact that the Reviser's Note fails to indicate any intention to effect what would be a far-reaching change as to residence of corporate plaintiffs.

This position is seconded in the recent opinion, Robert E. Lee & Co. Inc. v. Veatch, 301 F.2d 434 (4 Cir. 1961) cert. den. 371 U.S. 813 (1962). There the court concluded that Congress would have designed a more sweeping language for Section 1391(c), such as using "all corporations" in the second clause "instead of the restrictive term 'such corporation'", if Congress had intended to do more than codify the rule of Neirbo Co. v. Bethlehem Shipbuilding Corp. Ltd., 308 U.S. 165 (1939), [that a corporation waives its venue privilege not to be sued in a state by obtaining a license to do business there].

Because of the well-balanced forces of reason on either side of this controversy a gentlemanly disagreement will no doubt continue among the courts and commentators until settled by Congress or the Supreme Court. This court is persuaded by those who argue that Congress did not intend the sweeping change which plaintiffs assert and that for purposes of 28 U.S.C. 1391(c) residence is defined only for corporate defendants. The court also holds that the residence of a corporation for purposes of 28 U.S.C. 1391(c) is defined in Section 1391(c). The twenty-six corporations which are not incorporated in Delaware are not properly before the court as plaintiffs in the present action.

II. The PMA and Standing to Sue

The next jurisdictional objection raised by the defendants concerns the standing to sue of the PMA. It is asserted that there is no actual controversy between PMA and the defendants. The regulations promulgated by the Commissioner do not apply to the Association; it neither manufactures nor distributes drugs and it has no occasion, therefore, to either label drug products or advertise them.

The PMA claims to be harmed in a strict dollars and cents fashion by the disputed regulations. The Association points out that under Article III of its by-laws membership dues are based on the annual business of its members. Rules which affect the income of its members therefore affect PMA.

It is not in its own right, however, but as the representative of some 140 drug companies that this court finds PMA to have standing to sue. In National Motor Freight Traffic Association, Inc. v. United States, certain associations of motor carriers sought to set aside a decision of the Interstate Commerce Commission. The Government argued that the plaintiffs lacked standing to sue because they were associations of carriers rather than the carriers actually affected by the contested order. The lower court agreed with the Government's contention holding that the associations were not qualified to sue because they suffered no legally cognizable injury "except in the remote sense that the problems of their members are their concern." National Motor Freight Traffic Association, Inc. v. United States, 205 F. Supp. 592, 593 (D.C. 1962), aff'd. 372 U.S. 246 (1963).

The Supreme Court specifically rejected this ground for decision:

> "The appellants are associations of motor carriers, authorized under 49 USC § 5b, and perform significant functions in the administration of the Interstate Commerce Act, including the representation of member carriers in proceedings before the Commission. Since individual member carriers of appellants will be aggrieved by the Commission's order, and since appellants are proper representatives of the interests of their members, appellants have standing to challenge the validity of the Commission's order in the District Court." National Motor Freight Traffic Association, Inc. v. United States, 372 U.S. 246, 247 (1963).

The defendants here make much of the Supreme Court's reference to the authorization of motor carrier associations

under 49 U. S. C. § 5b. That section, however, does no more than insulate associations approved by the I.C.C. from violation of the antitrust laws. The crux of the opinion centers on the association as a representative of members who are individually harmed. In that sense, the PMA is similar to the associations in the Motor Freight Traffic case. It represents its members before the Food and Drug administration just as the motor carrier associations appeared in their members' behalf before the I.C.C.

The PMA is a proper representative of the interests of its member drug companies and has standing to challenge the validity of the defendant Commissioner's regulations in this Court.

III. Propriety of a Judicial Determination at This Time

Next the defendants put forward two related arguments which go to the propriety of adjudication at this stage in the proceedings. First, they say that there is no actual controversy between the plaintiffs and defendants as required by the Declaratory Judgment Act, 28 U.S.C. § 2201.[4] Second, they maintain that regulations interpretive in nature, are reviewable only as they may later be called into question in an enforcement action and not upon their promulgation.

If a regulation is final and a justiciable controversy exists as to its legality, the regulation is ripe for review. A justiciable controversy arises where a plaintiff is confronted with substantial present or imminent harm. The regulations before the court are final and a justiciable controversy exists. The very presence of a threat of harm makes the regulations ready for review. Davis, Administrative Law Treatise, § 21.07.

[4]Plaintiffs also claim to be here under § 10 of the Administrative Procedure Act, 5 U.S.C.A. § 1009. Since the court finds that they are properly here for a declaratory judgment it is not necessary to discuss the procedure for review of administrative rule making.

Defendants say that plaintiffs should not be permitted a declaratory judgment but should have to await an enforcement proceeding before they can call the contested regulations into question. Plaintiffs may have judicial review of interpretive regulations upon their promulgation without awaiting some ultimate enforcement. Frozen Food Express v. United States, 351 U.S. 40 (1956); Federal Trade Commission v. Nash-Finch Company, 288 F. 2d 407 (D.C. Cir. 1961). They need not await an action which would only make the threat of harm more pressing. The possibility of harm is already apparent to this court. The regulations in issue have placed them in a dilemma. Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution. It is of no moment that the Attorney General and not the Food and Drug Administration may enforce these rules. Nor does it matter that the Attorney General has not yet threatened enforcement. Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means. From the plaintiffs' point of view danger is imminent. The regulations of which they complain are ripe for review. The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril. To bar the courts to plaintiffs would be to do an injustice.

IV. The Attorney General as an Indispensable Party

The defendants next argue that the action cannot proceed because an indispensable party, the Attorney General, has not been joined. They point out that proceedings to enforce the Act or to restrain violations of the Act are to be brought in the name of the United States and that it is the Attorney General in his discretion who is granted authority to bring actions enforcing the Act.

Going back to first principles, indispensable parties are persons who have such an interest in a controversy that a final decree cannot be concluded without affecting that interest. 3 Moore, Federal Practice, 2150 (2d ed. 1963). It would seem unnecessarily cumbersome to hold that the Attorney General is such a party here. The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides. It is the defendants upon whom the benefit or blight of this decision will fall. The decree will expend itself on the defendants and not the Attorney General. The Attorney General is not a party indispensable to the instant litigation. See Federal Trade Commission v. Nash-Finch Company, supra.

V. The Present Controversy as an Unconsented Suit against the United States

Finally, defendants argue that this litigation is an unconsented suit against the United States.

They point out that the doctrine of sovereign immunity intervenes where the relief sought would interfere with the public administration or restrain the Government from acting or compel it to act. One of the cases cited in accord with this proposition is Larson v. Domestic and Foreign Commerce Corp., 337 U.S. 682 (1949). However, in Larson a significant exception is noted:

> "There may be, of course, suits for specific relief against officers of the sovereign which are not suits against the sovereign. * * * [W]here the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions. The officer is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden. His actions are 'ultra vires' his authority and therefore may be made the object of specific relief. It is important to note that in such cases the relief can be

granted, without impleading the sovereign, only because of the officer's lack of delegated power." Larson v. Domestic and Foreign Commerce Corp., Ibid. at 689-90.

In their complaint plaintiffs assert:

> "20. These regulations are arbitrary and capricious and not in accordance with law, and constitute an unwarranted and unlawful directive to plaintiff companies in excess of the defendants statutory authority and short of statutory right, and contrary to the statutory provisions on which they purport to be based. * * *"

The relief plaintiffs seek is a declaration that the statutory provisions on which the contested regulations are based "do not impose, or authorize the defendants to impose" the requirements which the regulations embody.

This court does not regard plaintiffs' claim that defendants have acted outside the scope of their authority as frivolous. As the Larson case notes, a suit challenging the unauthorized actions of government officials is not a suit against the United States. This action may go forward in the absence of the United States consent to be sued. See, Philadelphia Company v. Stimson, 223 U.S. 605 (1912).

The decision of the merits of this case does not require as lengthy discussion as does negotiation of the procedural maze leading to the merits. The proposition is simple: Congress has enacted legislation setting out rules which must be complied with if a drug is to be properly branded. The Commissioner of Food and Drugs has issued regulations interpreting the Act of Congress. Plaintiffs attack these regulations.

Regulations of the type with which the court is here concerned are valid unless unreasonable or inconsistent with the statute. Davis, Administrative Law Treatise, § 5.05 (1958). The statute and the disputed regulation are here set out.

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(e) (1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided,* That to the extent that compliance with the requirements of clause (A) (ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

* * *

"Section 1.104(g), 28 Fed. Reg. 6375 (June 20, 1963):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g) (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."

It is clear from the legislative history that the chief concern of Congress in enacting § 502(e) was the prominent display on labeling of the generic name of a drug. Congress intended to put an end to the previous common practice whereby drug companies would mention the generic name of a drug in an inconspicuous place in microscopic print in order to enhance the value of their own trade name. Congress took pains to assure that the generic name would be printed in type large enough to be seen. This was accomplished by specifying that the generic name be printed in type at least half as large as that used for the trade name.

Not only was Congress concerned with the size of the display of the generic name, it was also concerned with the position of that display. To that end, Congress required that the generic name be placed "prominently" on labeling. This was the concern of Congress. It is necessarily the concern of the court.

Congress did not specify what it meant by prominent display. Would one mention of the generic name in juxtaposition with the first mention of the trade name suffice? In printed matter comprising several pages should the generic name be mentioned on each page at least once, perhaps at the top of the page? Congress laid down no guide lines.

The defendant Commissioner has interpreted the language of Congress with a broad sweep. He says that the generic name must appear at every mention of the trade name. His interpretation is inconsistent with the statute.

The very word which he has seized on to support the every time requirement belies the argument that Congress intended the generic name be used every time. If Congress had intended that the generic name appear every time the brand name appears there would be no reason to use the word "prominently". The use of the word shows Congress was concerned that the generic name appear in a conspicuous place. If the generic name appeared with every mention of the trade name the requirement of prominence would be unnecessary.

The defendants maintain that the legislative history indicates the adoption by Congress of the every time requirement. They rely heavily upon a statement by Senator Kefauver in which the Senator explained the Conference Committee's rejection of an amendment offered by Congressman O'Brien in the House. The O'Brien amendment would have required that the generic name appear "at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug . . . is used. . . ." 108 Cong. Rec. 21081 (1962).

Kefauver explained,

> "This limitation was not accepted by the conferees. Thus the established name of a prescription drug must appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth." 108 Cong. Rec. 22039 (1962).

First, it is not clear that Kefauver's characterization of the O'Brien amendment as a limitation is accurate. Second, Kefauver's term "wherever" is not free from ambiguity. It could mean that the generic name must appear each time the trade name is mentioned. On the other hand, it could mean that the generic name must appear on a label or brochure or medicine box wherever the trade name is used. Apparently Kefauver favored the every time requirement. But nowhere

in the legislative history is there evidence to show that other members of the Congress favored the every time requirement or that they were aware that "prominently" should have a special meaning.

The views of Senator Kefauver, in this instance, cannot override what the court believes is the general Congressional intent. This is especially true since the expression of those views are circumscribed and open to doubt.

If Congress had meant that the generic name should appear with every mention of the trade name, it could have said so. It has not. It has said only that the generic name must appear prominently. The statute will not bear the interpretation which the defendants have put upon it.

Submit order in accordance herewith.

Wilmington, Delaware
April 30, 1964

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15,055

ABBOTT LABORATORIES; ET AL.

vs.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS, *Appellants*

(D.C. Civil No. 2737)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Present:

HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the District Court, filed June 1, 1964, except as to paragraph five, be, and the same is hereby vacated, the injunction dissolved, and the cause remanded to the District Court with directions to dismiss the complaint in accordance with the opinion of this Court.

ATTEST:

IDA O. CRESKOFF
Clerk

November 1, 1965

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15,054

ABBOTT LABORATORIES; ET AL.

vs.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U. S. A.) INC.; CARTER PRODUCTS, INC.; HOFFMAN-LA ROCHE, INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES,

Appellants

(D.C. Civil No. 2737)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE.

Present:

HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that paragraph five of the judgment of the District Court, filed June 1, 1964, be and the same is hereby affirmed.

ATTEST:

IDA O. CRESKOFF
Clerk

November 1, 1965

APPENDIX F

FEDERAL FOOD, DRUG, AND COSMETIC ACT

Section 502(e)(1), 52 Stat. 1050 (1938), as amended by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U.S.C. § 352(e)(1):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided,* That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

Section 502(n), added by § 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U.S.C. § 352(n):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed

matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act . . . ."